Participant Information Sheet

MEDICAL RESEARCH INSTITUTE OF NEW ZEALAND

Study title:	**Screening process for the rhinothermy in cold and flu studies**
Locality:	Ethics committee ref.:
Lead investigator:	Contact phone number:

You are invited to take part in a screening process to see if you are eligible for a study on the effect of inhaling warm, humidified air when you have the common cold or the 'flu. Whether or not you take part in the screening, and then the cold or flu study is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out at any time.

This Participant Information Sheet will help you to decide whether or not you would like to complete the screening tests for these studies. It sets out the tests that need to be done to see if you are eligible for either the cold or the flu study. We will go through this information with you and answer any questions you may have. As we need to make sure that you are enrolled into either the cold or flu study within 48 hours of developing your cold or flu symptoms, you may have only a short time to review this material before you decide whether to proceed or not. Before you decide, you may want to talk about the study with other people such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in the screening tests, you will be asked to sign an electronic Consent Form. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

If, after the screening tests, you are eligible for either the cold or the flu study, and you wish to take part, you will be provided with a separate consent form.

This screening process has been approved by the Southern Health and Disability Ethics Committee.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT WILL MY PARTICIPATION IN THE SCREENING PROCESS INVOLVE?

The screening process involves a number of steps;

1. We make sure you are the right age for the studies, and that you don't have any medical conditions or take any medications that might make you ineligible for either study

2. We make sure we are comfortable that you are able to complete all the tasks in either study
3. We make sure that you are happy for your usual doctor to be advised that you are enrolled in the cold or flu study if you DO end up in one of them.
4. We ask you to fill in two questionnaires
    a. One about flu symptoms
    b. One about common cold symptoms
5. Depending on the answers to the two symptom questionnaires, you may be asked to provide us with a sample from the back of your nose, which we will take with a swab through one nostril. This sample will be tested for the presence or absence of the flu virus.
6. If you have a negative test for the flu from your nose swab, and your cold symptom score meets the entry criteria, you will be advised that you are eligible for the cold study.
    a. You will receive a separate informed consent form for the cold study that will outline the process specifically for that study
7. If you have a positive test for the flu from your nose swab, and your flu symptom questionnaire meets the entry criteria, you will be advised that you are eligible for the flu study.
    a. Please note, female participants who reach this point will be asked to undertake a urinary pregnancy test, as pregnant females will be excluded from the flu study.
    b. All eligible participants will receive a separate informed consent form for the flu study that will outline the process specifically for that study.
8. There may be some people who have the wrong combination of cold or flu symptoms and flu test results, and will not be suitable for either study. If you are not suitable, you will be reimbursed for your time and travel.
9. If you are enrolled in either study, we will ask that for the first five days of the study, while you are taking one of the randomised treatments, you refrain from leaving the greater Wellington region (not beyond Upper Hut or Paraparaumu). If you have existing travel plans that require you to leave the greater Wellington region, you will be advised that you are not eligible for the study.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS SCREENING PROCESS?

The nostril swab we need to take is not painful, but some people may find it unpleasant or uncomfortable. They require a few seconds to perform and will be taken by trained staff.

We do not anticipate any other risks from participating in this screening process.

WHO PAYS FOR THE STUDY?

Participating in this screening process will not cost you anything.
You will be reimbursed to alleviate the costs of travel.

WHAT IF SOMETHING GOES WRONG?

If you are injured as a result of treatment given as part of this study, which is unlikely, you **will not** be eligible for compensation through ACC. However, compensation will be

available from the study sponsor, Fisher and Paykel Healthcare, in line with industry guidelines. We can give you a copy of these guidelines if you wish. You will be able to take action through the courts should you disagree with the amount of compensation offered.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

WHAT ARE MY RIGHTS?

Taking part in the screening is entirely voluntary (your choice). You are free to withdraw from screening at any time, without having to give a reason. The staff overseeing the screening process may also stop you from continuing if they decide it is not in your best interests to continue.

With respect to your personal information, your screening information will be labeled with a code. The link between the code and your name and address (identifying information) will only be held by the research staff. No material which could personally identify you will be used in any reports on this study.

WHAT HAPPENS AFTER THE SCREENING OR IF I CHANGE MY MIND?

Once you have been through this screening process, you will be told whether you are eligible or not for either of the studies. If you are eligible for one of the studies, you will receive a separate informed consent sheet for that study.

If you change your mind during this screening process, you will not be able to participate in either the cold or flu study.

Data collected during this screening process will be kept in a secure location by the MRINZ for at least 10 years following study completion. If you are enrolled in either the cold or flu study, the nostril swabs we have already taken will be stored, and may be sent to a laboratory in Christchurch New Zealand for confirmatory testing. The samples will be stored until the results of each study have been published, at which point they will be destroyed.

DEVICE GEOLOCATION

If you are eligible to participate in either the common cold or influenza study, you may be provided with a device (which delivers the warm, humidified air) for the purposes of the study. This device is property of the Sponsor and should not be taken or used outside of the area the study is being undertaken (the greater Wellington region). To enable the location of the device to be traced, the device has a geolocation function (similar to Google location services) which will collect location data. If the device is taken outside of the study area MRINZ and the Sponsor will be notified.

What information is collected?

Periodically, the approximate location of the device will be sent to a database on the Sponsor's secure server. The serial number of the device will also be collected. The

Sponsor will not have access to your personal details such as name, address or date of birth as these will only be held by MRINZ.

How will this information is collected and where is it stored?
The location data is collected directly from the device and is stored in a database on the Sponsor's secure server.

Who has access to this information?
Only a limited number of authorised employees of the Sponsor will be able to access the location data. However the location data will not be actively monitored, meaning it will not be checked or used unless the device is moved outside of the greater Wellington region or reported missing by MRINZ. If the device is moved outside of the greater Wellington region the Sponsor and MRINZ will be notified and the Sponsor will provide MRINZ with the location information, MRINZ will also be provided with the information if the device is reported missing.

What is this information used for?
This information is used to ensure the location of devices can be traced. As above, unless the device is moved outside of the greater Wellington region, or MRINZ reports the device missing, the information will not be monitored or accessed. If the device is moved outside of the greater Wellington region, or the device is reported missing by MRINZ, the information will be provided to MRINZ in order to locate the device.

When will this information be deleted?
Once the device is returned to MRINZ the Sponsor will delete the information.

If you are not willing to consent to the collection, use and storage of this information you may not be eligible to participate in these studies.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the screening process at any stage, you can contact:

Principal investigator
Phone:
E-mail:

Informed Consent Form

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Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this screening visit is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
If I decide to withdraw from the screening, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I consent to my GP or current provider being informed about my participation in the flu or cold study should I be enrolled, and of any significant abnormal results obtained during the study.
I agree to my (type of tissue) samples being sent overseas and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
I have read the section on geolocation of the device and consent to the collection, use and storage of this location data
I understand the compensation provisions in case of injury during the study.
I know who to contact if I have any questions about the study in general.

Declaration by participant:
I have read and agree to all of the above. I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____